UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE LUMIFY	Civil Action No. 21-16766 (RK) (RLS) (CONSOLIDATED) *Document Electronically Filed*

DEFENDANTS' OPENING MARKMAN SUBMISSION

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I. INTRODUCTION

The Parties require the Court's assistance to construe the meaning of two terms in U.S. Patent No. 11,596,600 ("the '600 patent"). The '600 patent is the third patent that Plaintiffs Bausch & Lomb, Inc., Bausch & Lomb Ireland Limited, and Eye Therapies, LLC (collectively, "Plaintiffs") have alleged would be infringed by Defendants' generic version of Bausch's LUMIFY® eye drops. When Defendants first filed their application with the U.S. Food and Drug Administration ("FDA") to market a generic version of LUMIFY® in the United States, the '600 patent did not exist—in fact, the application that ultimately issued as the '600 patent had not even been filed yet. Instead, Plaintiffs owned two patents that they claimed covered LUMIFY®—U.S. Patent Nos. 8,293,742 ("the '742 patent") and 9,259,425 ("the '425 patent"). Those patents are not currently at issue in this case. After Defendants filed two petitions for *inter partes* review challenging the validity of those patents before the Patent Trial and Appeal Board ("PTAB") in the U.S. Patent Office, Plaintiffs stipulated to dismissal of the '425 patent and gave Defendants a covenant not to sue on that patent. The *inter partes* review proceeding for the '742 patent concluded with the PTAB finding all claims in that patent unpatentable as obvious in a 70-page written decision. At Plaintiffs' request, the Parties have stipulated to stay all district court proceedings concerning the '742 patent, pending Plaintiffs' appeal of the PTAB's decision.[1]

The '600 patent at issue here is directed toward the same invention the Patent Trial and Appeal Board found unpatentable. It shares the same specification as the '742 and '425 patents and covers the same invention. Plaintiffs initially alleged that all 30 claims of the '600 patent would be infringed by Defendants' generic product. After reviewing Defendants' Non-Infringement and Invalidity Contentions, Plaintiffs have dropped all but two claims. Specifically,

[1] Plaintiffs' opening brief to the Federal Circuit is currently due January 5, 2024.

Plaintiffs allege that Defendants' generic product will infringe only claims 12 and 28 of the '600 patent ("the Asserted Claims").

The two phrases in dispute for purposes of claim construction—"in need of said reduction of eye redness" and "as the sole active ingredient"—are not particularly technical, nor scientific. Defendants propose these terms be construed based on their ordinary meaning, as reinforced by the patent's specification and prosecution history. In sharp contrast, Plaintiffs advance forced constructions in a transparent attempt to improperly redefine these plain English phrases. In doing so, Plaintiffs brazenly invite the Court to violate fundamental canons of claim construction. For the reasons explained below, the Court should decline Plaintiffs' invitation to rewrite the '600 patent claims.

II. FACTUAL BACKGROUND

A. Brimonidine Tartrate Has Been Used to Treat Eye Redness For Decades.

This case involves eye drops that contain drugs that reduce eye redness. The most common cause of eye redness is enlargement of blood vessels, referred to as vasodilation, near the front portion of the eye. For decades before Plaintiffs filed their first patent application, drugs known as "vasoconstrictors" were used to treat eye redness (which is also commonly known as conjunctival hyperemia or ocular hyperemia[2]). *See* '600 patent at 1:20–2:3. Vasoconstrictors cause blood vessels to shrink, allowing less blood through them. *Id.* at 2:4–7. Constricting blood vessels in the white part of the eye has the result of reducing the appearance of redness in the eye. The use of vasoconstrictor-based eye drops to reduce eye redness dates back to at least the late 1980s when FDA required labels for over-the-counter ("OTC") vasoconstrictor eye drops to identify the product as a "redness reliever." Common OTC redness relievers like Visine® and

[2] Hyperemia refers to an "excess of blood in a body part." *Hyperemia*, Merriam-Webster Dictionary (2023).

Clear Eyes®—both of which contain vasoconstrictors as the active ingredient—have been commercially available for decades.

The particular vasoconstrictor at issue here is an old, off-patent drug called brimonidine. Brimonidine was first approved by the FDA as an eyedrop in 1996 (known by the brand name Alphagan®, which was sold by Allergan, Inc.). At the time, Alphagan®, which contained a different concentration of brimonidine than what is claimed in the '600 patent, was used to lower intraocular pressure in patients with glaucoma. In the decade that followed the commercial release of Alphagan®, brimonidine was among the most well-studied and well-characterized drugs on the market. By at least the early 2000s, it was known that α-2 adrenergic receptor agonists, such as brimonidine, could cause vasoconstriction. Indeed, the specification of the '600 patent concedes, "[i]t is a ***known property*** of all [α-]adrenergic receptor agonists, ***including brimonidine***, to cause vasoconstriction." '600 patent, 2:4–7 (emphasis added).

B. The '600 Patent Is Directed to the Use of an Obvious Concentration of Brimonidine Tartrate to Treat Eye Redness.

The '600 patent is entitled "Vasoconstriction Compositions and Methods of Use." The sole listed inventor is Gerald Horn, and the patent "generally relates to compositions for inducing vasoconstriction." '600 patent at abstract. The applicant of the '600 patent sought to focus the purported invention on the use of "low concentrations" of brimonidine for eye redness reduction. Specifically, the focus was directed to "compositions [that] comprise highly selective [α]-2 adrenergic receptor agonists, at low concentrations, such as below 0.05% weight by volume" and preferably at a "pH between 5.5 to 6.5." '600 patent at abstract. The language of the sole independent claim and the Asserted Claims, which are both dependent claims, is reproduced below:

Claim	Language
1 (not asserted)	A method for reducing eye redness in a human subject having ocular hyperemia, comprising topically administering to an eye of said human in need of said reduction of eye redness an ocular drop comprising about 0.025% weight by volume brimonidine as the sole active ingredient, wherein the ocular drop has a pH between 5.5 to 6.5.
12 (asserted)	The method of claim 1, wherein the eye redness of said human is not associated with an ocular disease or the result of a surgical procedure on the eye.
28 (asserted)	The method of claim 1, wherein the weight by volume brimonidine is 0.025%.

Asserted claim 12, which depends from claim 1, is directed to "an ocular drop comprising about 0.025% weight by volume brimonidine as the sole active ingredient," and claim 28, which also depends from claim 1, narrows that range "wherein the weight by volume brimonidine is 0.025%." In both instances, the clinical effect of the concentration of brimonidine used to reduce eye redness remains substantially the same.

III. SUMMARY OF CLAIM CONSTRUCTION DISPUTES

The Parties dispute the construction of two terms: "in need of said reduction of eye redness" and "as the sole active ingredient." Although Plaintiffs contend that these terms should be afforded their "plain and ordinary meaning," Plaintiffs' proposed constructions of the two terms is neither plain nor ordinary. A chart of the proposed terms and the Parties' positions is included below:

Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
"in need of said reduction of eye redness"	Plaintiffs propose that this phrase, as it is used in the claims of the '600 patent, should be given its plain and ordinary meaning, as understood by a person of ordinary skill in the art at the time of invention consistent with the intrinsic record, including the specification and file history, which a person of ordinary skill in the art would have understood to mean "a human having ocular hyperemia, where such hyperemia is reduced by vasoconstriction"	"having ocular hyperemia"
"as the sole active ingredient"	Plaintiffs propose that this phrase, as it is used in the claims of the '600 patent, should be given its plain and ordinary meaning, as understood by a person of ordinary skill in the art at the time of invention consistent with the intrinsic record, including the specification and file history, which a person of ordinary skill in the art would have understood to mean "[administering brimonidine] as the only active ingredient to affirmatively reduce redness in a person having ocular hyperemia"	"without any other active ingredient in the ocular drop"

As for the first disputed term, the Parties agree that "in need of said reduction of eye redness" refers to a human "having ocular hyperemia." The Parties disagree, however, regarding whether the additional language Plaintiffs seek to read into the term—i.e., "where such hyperemia is reduced by vasoconstriction"—is appropriate. Plaintiffs seek to introduce a limitation from the written description into the claim—a practice barred by controlling Federal Circuit precedent. *See SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1340 (Fed. Cir. 2001) (citing *Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998)) ("one of the cardinal sins of patent law—reading a limitation from the written description into the claims").

Regarding the second disputed term, Defendants' construction tracks the plain English meaning of the claim language. The relevant portion of the claim reads: "an ocular drop comprising about 0.025% weight by volume brimonidine as the sole active ingredient." That is, the only active ingredient *in the ocular drop* is brimonidine. Accordingly, Defendants' construction makes clear that the ocular drop contains no "other active ingredient" besides brimonidine. In contrast, Plaintiffs attempt to use the claim construction process to redefine the entire scope of the claim: that the method claimed is limited to administration of brimonidine where it is "the only active ingredient to affirmatively reduce redness in a person having ocular hyperemia." Plaintiffs' construction ignores that the term at issue is part of a phrase in the claim that defines what is (or, more precisely, is not) contained in the "ocular drop." Plaintiffs' construction also introduces the concept of "affirmatively reduc[ing] eye redness," which appears nowhere in the claim language. And Plaintiffs' construction needlessly repeats language—"a person having ocular hyperemia"—that serves no apparent purpose. Plaintiffs' additional verbiage is not supported by the intrinsic evidence of the '600 patent and should be rejected.

IV. LEGAL STANDARDS

Claim construction plays a crucial role in a patent infringement action—it is the first step of both the invalidity and infringement analysis. *See Wilson Sporting Goods Co. v. Hillerich & Bradsby Co.*, 442 F.3d 1322, 1326 (Fed. Cir. 2006) ("[P]atent infringement analysis involves two steps: claim construction, and application of the construed claim to the accused process or product."); *Akamai Techs., Inc. v. Cable & Wireless Internet Servs., Inc.*, 344 F.3d 1186, 1195 n.4 (Fed. Cir. 2003) ("Before the factual question of anticipation may be addressed, a court must first properly construe the claims before it."). As the claims of the patent "define the scope of the patented invention," *Vitronics Corp v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996), construing the claims elucidates what rights "the patent confers on the patentee to exclude others

from making, using, or selling the protected invention." *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989).

Claim construction is a question of law. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 325 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388–91 (1996)). When "the parties present a fundamental dispute regarding the scope of a claim term, it is the court's duty to resolve it." *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362–63 (Fed. Cir. 2008). The court must determine what the claim terms mean, using a certain set of interpretative tools. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979–80 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). Generally, claim terms are given their "ordinary and customary meaning," which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). It is not enough to simply construe the claim as having its "ordinary and customary meaning" without defining that meaning. *See O2 Micro*, 521 F.3d at 1361–62; L. Pat. R. 4.2(a) ("[T]he parties shall simultaneously exchange . . . constructions for each term for which 'plain and ordinary' meaning is asserted."). The court determines this meaning by "reviewing the same resources as would that person, *viz.*, the patent specification and the prosecution history." *Phillips*, 415 F.3d at 1313 (internal quotations and citations omitted). What the person of ordinary skill in the art would understand a claim term to mean "provides an objective baseline from which to begin claim interpretation." *Id.*

In construing a claim, the court should first look at the claim itself, as "the context in which a term is used in the asserted claim can be highly instructive." *Id.* at 1314. In addition, claims must "be read in view of the specification, of which they are part." *Id.* at 1315. The specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the

single best guide to the meaning of a disputed term." *Id.* This is because patent law requires that a patentee set out the claimed invention in "full, clear, concise, and exact terms" in the specification. *See id.* at 1316. It is improper, however, for a court to "read[] limitations" from the specification into the claims where those limitations are not included in the claims themselves. *Id.* at 1322–23.

In addition, the court may also consult the patent's prosecution history, which consists of the "complete record of the proceedings before the [Patent Office] and includes the prior art cited during the examination of the patent." *Id.* at 1317. The prosecution history "provides evidence of how the [Patent Office] and the inventor understood the patent." *Id.* However, because the prosecution history "represents an ongoing negotiation between the [Patent Office] and the applicant, . . . it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.* (internal citations omitted). This combination of the claim language itself, the specification, and the prosecution history is referred to as "intrinsic evidence." *See id.*

The court may rely upon additional extrinsic evidence, including "expert and inventor testimony, dictionaries, and learned treatises." *Id.* (internal quotations omitted). Although such extrinsic evidence can provide useful background, courts "have viewed extrinsic evidence in general as less reliable than the patent and its prosecution history in determining how to read claim terms." *Id.* at 1318. The Federal Circuit cautions that extrinsic evidence must be viewed "in the context of the intrinsic evidence," as "undue reliance of extrinsic evidence poses the risk" that it will change the meaning, and ultimately the scope, of the claims. *Id.* at 1318–19.

V. QUALIFICATIONS OF A POSA

"In approaching claim construction, we must always be conscious that our objective is to interpret the claims from the perspective of one of ordinary skill in the art." *Dayco Prods., Inc. v. Total Containment, Inc.*, 258 F.3d 1317, 1324 (Fed. Cir. 2001). A person of ordinary skill in the

art ("POSA") is a "legal construct [that] is akin to the 'reasonable person' used as a reference in negligence determinations. The legal construct also presumes that all prior art references in the field of the invention are available to this hypothetical skilled artisan." *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). "A person of ordinary skill is also a person of ordinary creativity, not an automaton," meaning that "in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420–21 (2007).

A POSA at the time of the alleged invention claimed in the '600 patent would be a composite person (or team) with experience as a medical doctor and pharmaceutical formulator. The medical doctor would have experience as an ophthalmologist with at least three-to-four years of experience in LASIK surgery, clinical trials, and U.S. FDA regulation of eye products, with experience in using topical brimonidine and apraclonidine, as well as topical vasoconstrictors such as naphazoline and tetrahydrozoline. The pharmaceutical formulator would have a bachelor's degree in pharmaceutics or a related discipline with about three-to-five years of work experience in ophthalmic formulations, or a comparable level of education or training (such as a Ph.D. with one or two years of experience in this area).

In its Final Written Decision for the related '742 patent, the PTAB determined that a POSA "may be represented by a team of individuals with experience and various skills relating to eye care, including, *inter alia*, the medical and pharmaceutical arts." *Slayback Pharma LLC v. Eye Therapies, LLC*, IPR2022-00142, Paper 77, at 8 (P.T.A.B. May 15, 2023) (*see* Declaration of Linnea P. Cipriano, Exhibit A). The PTAB also determined that "a POSA would have had access to team members with experience in chemistry, designing and formulating ophthalmic formulations, and/or in administering such formulations to treat ocular conditions obtained by

some combination of education and work experience." *Id.* Any nominal differences between the definition proposed in the previous paragraph and the PTAB's definition are immaterial to the claim construction issues in this case.

VI. ANALYSIS OF THE DISPUTED CLAIM TERMS OF THE '600 PATENT

A. "in need of said reduction of eye redness"

Claim Term for Construction	Defendants' Proposed Construction	Plaintiffs' Proposed Construction
"in need of said reduction of eye redness" Claims 12, 28 (language appears in Claim 1, from which the Asserted Claims depend directly)	"having ocular hyperemia"	"a human having ocular hyperemia, where such hyperemia is reduced by vasoconstriction"

Claim 1 of the '600 patent (from which claims 12 and 28 depend) is directed toward "[a] method for reducing eye redness in a human subject" for a "human in need of reduction of eye redness." The Parties agree that a "human in need of reduction of eye redness" is a human "having ocular hyperemia." As explained above, "ocular hyperemia" is the medical term for eye redness. Thus, the Parties agree that a "human in need of reduction of eye redness" is a human who is suffering from eye redness (or "ocular hyperemia"). The Parties' proposed constructions diverge, however, in that Plaintiffs seek to improperly import additional limitations into their proposed construction. Specifically, Plaintiffs seek to insert a requirement that "such hyperemia is reduced" and that it is "reduced by vasoconstriction." Plaintiffs' attempt to read additional limitations into the claim violates basic tenets of claim construction and finds no support in the specification or prosecution history.

Plaintiffs' proposed construction should be rejected because it requires "committ[ing] one of the cardinal sins of patent law—reading a limitation from the written description into the

claims." *SciMed Life Sys.*, 242 F.3d at 1340. Claim 1 refers to a human "having ocular hyperemia" and describes that human as being "in need of said reduction of eye redness" without qualification:

> A method for reducing eye redness in a human subject *having ocular hyperemia*, comprising topically administering to an eye of said human *in need of said reduction of eye redness* an ocular drop comprising about 0.025% weight by volume brimonidine as the sole active ingredient, wherein the ocular drop has a pH between 5.5 to 6.5.

'600 patent at claim 1 (emphasis added). There is nothing in the claim language that requires that the hyperemia actually be reduced—i.e., that the treatment works or is efficacious. Nor is there any requirement in the claim that redness is reduced because of vasoconstriction.

First, Plaintiffs' proposed construction improperly requires that the hyperemia actually "is reduced" by the method. In effect, Plaintiffs seek to add a requirement that the treatment is efficacious—that is, that it actually worked. But the claims as written have no such efficacy requirement. The claims recite only the steps of the method—there is nothing in the claims that requires any redness to actually be reduced. Indeed, courts have repeatedly rejected arguments that attempt to read efficacy limitations into claims where such limitations are absent. *See, e.g.*, *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1330 (Fed. Cir. 2012) ("Neither the claims, the specification, nor the prosecution history suggest that the claimed perfusion must satisfy certain safety or efficacy standards. We previously have refused to impose such limitations when not required by the language of the claims or the specification, . . . and decline to do so here."); *Mitsubishi Chem. Corp. v. Barr Lab'ys, Inc.*, 435 Fed. App'x 927, 934–35 (Fed. Cir. 2011) (declining to limit a claim to only compounds that are "safe, effective, and reliable for use in humans" because there was no support for such a limitation in the specification and the property is not "necessary for patentability"); *Iovate Health Scis., Inc. v. Bio-Engineered Supplements & Nutrition, Inc.*, 586 F.3d 1376, 1382 (Fed. Cir. 2009) (refusing to read an effectiveness requirement into the preamble of a claim where the claim did not "require any further measurement or

determination of any result achieved by administering the claimed composition"); *Celgene Corp. v. Hetero Labs Ltd.*, 17-cv-3387, 2020 WL 3249117, at *5 (D.N.J. June 16, 2020) (declining to read an efficacy requirement into the term "treating multiple myeloma" where "nothing in the claim language, the specification, or the prosecution history warrants reading into the claim an efficacy limitation based on the preamble").

Plaintiffs' improper attempt to create an efficacy limitation where none exists is even more glaring because their new limitation—"is reduced"—is divorced from the claim term that is actually in dispute. A human that is "in need of said reduction of eye redness" is "in need" regardless of whether the yet-to-be performed method actually works. Thus, Plaintiffs' first imported limitation has no bearing on whether the human is "in need of said reduction of eye redness."

Second, Plaintiffs' proposed construction also requires that the hyperemia is reduced "by vasoconstriction." This requirement likewise appears nowhere in the claims. As highlighted above, the claims recite only the steps of the method and the requirement that the method be performed on a human "in need of said reduction of eye redness," i.e., a human "having ocular hyperemia." The claims do not specify the mechanism of action by which the hyperemia must be reduced. To be sure, brimonidine was a known vasoconstrictor, but that is not a reason to include that requirement into these patent claims. Once again, Plaintiffs' imported limitation is wholly divorced from the claim term in dispute. A human "in need of said reduction of eye redness" is "in need" regardless of the mechanism of action by which the yet-to-be performed method of reducing redness works. Thus, Plaintiffs' second imported limitation also has no bearing on whether the human is "in need of said reduction of eye redness."

The Parties agree that a human who is "in need of said reduction of eye redness" is a human who simply has "ocular hyperemia." The construction of this term should end there. Because Plaintiffs' proposed construction amounts to an improper attempt to import limitations into the claims, the Court should reject the additional language in Plaintiffs' proposal and construe this term according to Defendants' construction: "having ocular hyperemia."

B. "as the sole active ingredient"

Claim Term for Construction	Defendants' Proposed Construction	Plaintiffs' Proposed Construction
"as the sole active ingredient" Claims 12, 28 (language appears in Claim 1, from which the Asserted Claims depend directly).	"without any other active ingredient in the ocular drop"	"[administering brimonidine] as the only active ingredient to affirmatively reduce redness in a person having ocular hyperemia"

The Parties' dispute regarding this claim term centers around whether brimonidine is the sole active ingredient *in the ocular drop* (Defendants' proposal) or the sole active ingredient *for the entire method* (Plaintiffs' proposal). This distinction became clear in Plaintiffs' Response to Defendants' Invalidity Contentions, where Plaintiffs argued that the '600 patent is not obvious over various prior art references that disclosed the use of brimonidine because those references purportedly disclosed the use of brimonidine in connection with surgeries where patients were also given other drugs in connection with the surgeries. Plaintiffs argued that prior art in which a patient was administered any other drug that may have an impact on inflammation or redness would not fall within the scope of the claims. (*See* Declaration of Linnea P. Cipriano, Exhibit B, Plaintiffs' Response to Defendants' Invalidity Contentions Regarding U.S. Patent No. 11,596,600, at 32–33, 39–41, 50–59, 65–66, 72–74.) This reading of the claims distorts the plain language of the "sole active ingredient" claim term. Defendants' proposed construction is instead faithful to

that plain language because it defines the term in the context of the claim—not in spite of the claim.

Claim 1 of the '600 patent recites "[a] method for reducing eye redness in a human subject having ocular hyperemia, comprising topically administering to an eye of said human in need of said reduction of eye redness **an ocular drop** comprising about 0.025% weight by volume brimonidine **as the sole active ingredient**, wherein the ocular drop has a pH between 5.5 to 6.5." (emphasis added.) The plain language of the claim defines the scope of the claim by reciting "an ocular drop" and using "comprising" to describe certain features that must be present in the "ocular drop." Thus, the "ocular drop" has three requirements as claimed: (i) it contains "about 0.025% weight by volume brimonidine," (ii) brimonidine is "the sole active ingredient," and (iii) it has "a pH between 5.5 to 6.5." The plain language of the claim is agnostic regarding whether a physician (or patient) as part of the treatment is administering other drugs, provided those drugs are not in the same ocular drop as brimonidine.

Plaintiffs' proposed construction is incorrect because it would make the entire claim incoherent.[3] If the term "as the sole active ingredient" were to be substituted for Plaintiffs' proposed construction, the meaning of the entire claim would be altered. Plaintiffs' proposed claim would read:

> A method for reducing eye redness in a human subject having ocular hyperemia, comprising topically administering to an eye of said human in need of said reduction of eye redness an ocular drop comprising about 0.025% weight by volume brimonidine [**"[administering brimonidine] as the only active**

[3] "[T]he context in which a term is used in the asserted claim can be highly instructive." *Phillips*, 415 F.3d at 1303. Courts reject constructions where the proposed "construction makes little sense when read in the context of the entire claim." *Amgen Inc. v. Mylan Inc.*, 2:17-cv-01235, 2018 WL 6061213, at *15 (W.D. Pa. Nov. 20, 2018) (rejecting construction that was inconsistent with the claim language and specification); *see also Uniloc 2017 LLC v. Google LLC*, 2:18-cv-00491-JRG-RSP, 2020 WL 569857, at *3 (E.D. Tex. Feb. 5, 2020) ("Plaintiff's original construction is improper when read in the context of the claim language").

> **ingredient to affirmatively reduce redness in a person having ocular hyperemia**,"] wherein the ocular drop has a pH between 5.5 to 6.5.

Under Plaintiffs' proposed construction, the "ocular drop" now only has two requirements instead of three: (i) it contains "about 0.025% weight by volume brimonidine" and (ii) it has "a pH between 5.5 to 6.5." Rather than cabining the claim limitation "brimonidine as the sole active ingredient" to the "ocular drop" as the claim plainly requires with its use of "an ocular drop comprising," Plaintiffs' proposed construction plucks the limitation that brimonidine be the sole ingredient from its natural context—applying only to the ocular drop—and transforms it to apply to the entire method claim.

This transformation is inconsistent with the plain language of the claim because it renders meaningless the express limitation that the ocular drop contains brimonidine as the sole active ingredient. Under Plaintiffs' proposed construction, not only is the entire method now restricted to just brimonidine as the "only active ingredient to affirmatively reduce redness in a person having ocular hyperemia," but Plaintiffs' construction also reads out the restriction that brimonidine be the sole active ingredient in the ocular drop—meaning that a POSA could include other active ingredients in the ocular drop so long as those ingredients do not "affirmatively reduce redness in a person having ocular hyperemia." This construction ignores the plain language of the claim requiring "an ocular drop comprising . . . brimonidine as the sole active ingredient." "When the language of a claim is clear, as here, and a different interpretation would render meaningless express claim limitations, [courts should] not resort to speculative interpretation based on claims not granted." *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950–51 (Fed. Cir. 2006) (internal quotations omitted).

Another reason the Court should reject Plaintiffs' construction is that it improperly introduces the indefinite limitation "to affirmatively reduce redness" into the claim even though

there is no support for that limitation in the '600 patent. The term "affirmatively" does not even appear anywhere in the '600 patent, and Plaintiffs provide no explanation as to what that term means. A POSA would have no understanding as to the metes and bounds of the limitation. Plaintiffs' proposed construction would unnecessarily introduce an indefinite limitation into the claims where one is not necessary, which further evidences that the proposed construction is incorrect.[4]

VII. CONCLUSION

For at least the foregoing reasons, Defendants respectfully request that the Court adopt Defendants' proposed constructions and reject Plaintiffs' proposals.

[4] To the extent the Court adopts Plaintiffs' proposed construction of this term, Defendants reserve the right to argue that this term renders the claims invalid as indefinite under 35 U.S.C. § 112.

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